Amended Claims

1. A controlled release pharmaceutical composition for oral administration of tolperisone to a subject containing

(a) a core which includes

i) the racemic tolperisone, or pharmaceutically acceptable salts thereof, in the range of 100-500 mg to provide a stereoselective disposition of tolperisone enantiomers in the blood plasma of the subject and

ii) the controlled release agent selected from the group Eudragit RS, Eudragit L, Eudragit S and

(b) a controlled release coating selected from the group Eudragit RS , Eudragit L, which is associated with the core.

2. The controlled release pharmaceutical composition of claim1 wherein the stereoselective disposition of tolperisone enantiomers in the blood plasma of the subject is analyzed by the plasma area under the curve (AUC) concentration ratio of R-tolperisone to S-tolperisone as 3:1 or higher.

3. The controlled release pharmaceutical composition of claim 1 wherein the stereoselective disposition of tolperisone enantiomers in the blood plasma of the subject is analyzed by the plasma area under the curve (AUC) concentration ratio of R-tolperisone to S-tolperisone as 4:1 or higher.

4. The controlled release pharmaceutical composition of claim 1 wherein the amount of racemic tolperisone is within the range of 100-249 mg.

5. The controlled release pharmaceutical composition of claim 4 wherein the controlled release of the racemic tolperisone results in no more than 55% by weight of the racemic tolperisone at 2 hours (measured using the USP Basket

Method at 75 rpm in 1,000 ml 0.1 HCL at 37° C).

6. The controlled release pharmaceutical composition of claim 4 wherein the controlled release of the racemic tolperisone results in no more than 45% by weight of the racemic tolperisone at 2 hours (measured using the USP Basket Method at 75 rpm in 1,000 ml 0.1 HCL at 37° C).

7. The controlled release pharmaceutical composition of claim 1 wherein the amount of racemic tolperisone is within the range of 250-500 mg.

8. The controlled release pharmaceutical composition of claim 7 wherein the composition exhibits an in vitro dissolution profile (measured using the USP Basket Method at 75 rpm in 1,000 ml 0.1 N HCL at 37° C) where after 2 hours no more than 20% (by weight) of the racemic mixture is released.

9. The controlled release pharmaceutical composition of claim 7 wherein the composition exhibits an in vitro dissolution profile (measured using the USP Basket Method at 75 rpm in 1,000 ml 0.1 N HCL at 37° C) where after 2 hours no more than 30% (by weight) of the racemic tolperisone is released.

10. The controlled release pharmaceutical composition of claim 7 wherein the composition further exhibits an in vitro dissolution profile (measured using the USP Basket Method at 75 rpm in 1,000 ml 0.1 N HCL at 37° C) where after 4 hours no more than 60% (by weight) of the racemic tolperisone has been released.

11. The controlled release pharmaceutical composition of claim 1 comprising racemic tolperisone in the amount of 100-200 mg, or pharmaceutically acceptable salts thereof, wherein the composition exhibits an in vitro dissolution profile (measured using the USP Basket Method at 75 rpm in 1,000 ml 0.1 N HCL at 37 ° C) where after 2 hours no more than 45% (by weight) of the racemic tolperisone is released.

12. The controlled release pharmaceutical composition of claim 11 wherein the composition exhibits an in vitro dissolution profile (measured using the USP Basket Method at 75 rpm in 1,000 ml 0.1 N HCL at 37° C) where after 2 hours no more than 55% (by weight) of the racemic tolperisone is released.

13. The controlled release pharmaceutical composition of claim 1 comprising racemic tolperisone in the amount of 201-500 mg, or pharmaceutically acceptable salts thereof, wherein the composition exhibits an in vitro dissolution profile (measured using the USP Basket Method at 75 rpm in 1,000 ml 0.1 N HCL at 37° C) where after 2 hours no more than 20% (by weight) of the racemic mixture is released.

14. The controlled release pharmaceutical composition of claim 13 wherein the composition exhibits an in vitro dissolution profile (measured using the USP Basket Method at 75 rpm in 1,000 ml 0.1 N HCL at 37° C) where after 2 hours no more than 30% (by weight) of the racemic tolperisone is released.

15. The controlled release pharmaceutical composition of claim 14 wherein the composition further exhibits an in vitro dissolution profile (measured using the USP Basket Method at 75 rpm in 1,000 ml 0.1 N HCL at 37° C) where after

4 hours no more than 60% (by weight) of the racemic tolperisone has been released.

16. A controlled release pharmaceutical composition for oral administration to a subject of tolperisone comprising:

a core including about 125-175 mg of racemic tolperisone, or pharmaceutically acceptable salts thereof, and a controlled release agent comprising a homogeneous mixture of about 9-12 mg of Eudragit S, about 1.5-2.25 mg Eudragit RS and about 9-12 mg Eudragit L; and

a controlled release coating comprising about 1-4 mg Eudragit L associated with the core to provide for controlled release of the racemic tolperisone upon such oral administration resulting in stereoselective disposition of tolperisone enantiomers in the blood plasma of the subject.

17. The controlled release table of claim 16 wherein the controlled release agent comprises a homogeneous mixture of about 10.5 mg Eudragit S, about 1.88 mg Eudragit RS and about 105 mg Eudragit L and the controlled release coating comprises about 2 mg Eudragit L.

18. A controlled release pharmaceutical composition for oral administration to a subject of tolperisone comprising:

a core including about 300 mg of racemic tolperisone, or pharmaceutically acceptable salts thereof, and a controlled release agent comprising a homogeneous mixture of about 2.5-5 mg Eudragit RS, about 20-22 mg Eudragit L and about 20-22 mg Eudragit S; and

a controlled release coating comprising about 4-10 mg Eudragit RS associated with the core to provide for controlled release of the racemic tolperisone upon such oral administration resulting in stereoselective disposition of tolperisone enantiomers in the blood plasma of the subject.

19. The controlled release pharmaceutical composition of claim 18 wherein the controlled release agent comprises about 3.75 mg Eudragit RS, about 21 mg Eudragit L and about 21 mg Eudragit S and the controlled release coating comprises about 4.5 mg of Eudragit RS.

20. Use of the controlled release pharmaceutical composition in accordance with one of claims 1 until 19 for the manufacture of a muscle relaxant

21. Use of the controlled release pharmaceutical composition in accordance with one of claims 1 until 19 for the manufacture of a medicament for treating a chronic disease.

22. Use of the controlled release pharmaceutical composition in accordance with one of claims 1 until 19 for the manufacture of a medicament for treating a chronic disease selected from the group consisting of multiple sclerosis, fibromyalgia, Parkinson's disease, climacteric symptoms, spasticity resulting from a stroke, spasticity resulting from neurological diseases, cervical syndrome, lumbago, cervico-brachial syndrome, osteoporosis, arthritis, rheumatic diseases such as soft tissue rheumatism and chronic polyarthritis.